NB: this is a summary translation of the press release original drafted in Japanese for the disclosure required in compliance with the TSE regulations.

Non-consolidated Financial Results for the Nine Months Ended September 30, 2024 [Japanese GAAP]

November 8, 2024

Company name: Oncolys BioPharma Inc.
Stock exchange listing: Tokyo Stock Exchange
Code number: 4588
URL: https://www.oncolys.com
Representative: Yasuo Urata, President & CEO
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Scheduled date of commencing dividend payments: —
Availability of supplementary briefing material on financial results: No
Schedule of financial results briefing session: No

(Amounts of less than one million yen are rounded down.)

1. Financial Results for the Nine Months Ended September 30, 2024 (January 1, 2024 to September 30, 2024)

(1) Operating Results (% indicates changes from the previous corresponding period.)

	Net sales		Operating profit		Ordinary profit		Profit	
Nine months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
September 30, 2024	31	(50.2)	(1,230)	–	(1,243)	–	(1,246)	–
September 30, 2023	63	(92.0)	(1,311)	–	(1,270)	–	(1,272)	–

	Basic earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
September 30, 2024	(59.56)	–
September 30, 2023	(73.15)	–

(2) Financial Position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of September 30, 2024	2,397	1,962	81.5
As of December 31, 2023	2,040	1,474	71.5

(Reference) Equity: As of September 30, 2024: ¥1,953 million
As of December 31, 2023: ¥1,459 million

2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended December 31, 2023	–	0.00	–	0.00	0.00
Fiscal year ending December 31, 2024	–	0.00	–		
Fiscal year ending December 31, 2024 (Forecast)				0.00	0.00

(Note) Revision to the forecast for dividends announced most recently: No

3. Financial Results Forecast for the Fiscal Year Ending December 31, 2024 (January 1, 2024 to December 31, 2024)

Financial results forecast is not disclosed due to the difficulty of making reasonable estimates. For details, please see "1. Qualitative Information on Quarterly Financial Results for the Period under Review (3) Explanation of Financial Results Forecast and Other Forward-looking Information" on page 2 of the supplementary material.

*** Notes:**

(1) Accounting policies adopted specially for the preparation of quarterly financial statements: No

(2) Changes in accounting policies, changes in accounting estimates and retrospective restatement
1) Changes in accounting policies due to the revision of accounting standards: No
2) Changes in accounting policies other than 1) above: No
3) Changes in accounting estimates: No
4) Retrospective restatement: No

(3) Total number of issued shares (common shares)
1) Total number of issued shares at the end of the period (including treasury shares):
September 30, 2024: 22,726,862 shares
December 31, 2023: 19,717,100 shares

2) Total number of treasury shares at the end of the period:
September 30, 2024: 94,738 shares
December 31, 2023: 88,738 shares

3) Average number of shares during the period:
Nine months ended September 30, 2024: 20,932,636 shares
Nine months ended September 30, 2023: 17,399,785 shares

* Review of the attached quarterly financial statements by certified public accountants or an audit corporation: No

* Explanation of the proper use of financial results forecast and other notes

(Note regarding forward-looking statements, etc.)

The earnings forecasts and other forward-looking statements herein are based on information available to the Company at the time of the release of these materials and certain assumptions deemed reasonable, and do not represent a commitment from the Company that they will be achieved. In addition, actual financial results, etc. may differ significantly due to a wide range of factors. For the assumptions used in forecasting financial results and notes regarding the use of financial forecasts, etc., please see "1. Qualitative Information on Quarterly Financial Results for the Period under Review (3) Explanation of Financial Results Forecast and Other Forward-looking Information" on page 2 of the supplementary material.

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1. Qualitative Information on Quarterly Financial Results for the Period under Review

(1) Explanation of Business Results

During the nine months ended September 30, 2024, while the Japanese economy expected to see a recovery in production of automobiles mainly at major companies and a rebound of demand for semiconductors as well as contained procurement costs due to the impact of the yen's appreciation owing to the Federal Reserve Boards' interest rate cuts, it remained flat due to the impact of a slowdown of overseas demand such as the one in China. Furthermore, as for the overseas economy, as risk factors in the global economy have increased such as the escalation of Israel's conflict into Lebanon in addition to the political factor including the U.S. presidential election, the volatile situation will likely continue.

Under these circumstances, the Company has been pursuing a vision of "Providing new options to future cancer treatments, and leaving our footprint in the history of cancer treatment through those achievements." In particular, the Company is promoting research, development, and business activities with a focus on oncolytic virus OBP-301. The Company moves from the conventional single business model dependent on licenses to a "hybrid business model" that combines a pharmaceutical company-type business model and a license-type business model with the development of the domestic business of OBP-301 as a pharmaceutical company-type business model.

In addition, concerning LINE-1 inhibitor OBP-601 (censavudine), Transposon Therapeutics, Inc. (hereinafter "Transposon") is conducting clinical trials at its own expense based on a license agreement and proceeding with business activities.

For details of the Company's activities, please refer to "3. Supplemental Information (1) Research and development activities."

For the nine months ended September 30, 2024, the Company recorded net sales of ¥31,384 thousand (net sales of ¥63,038 thousand in the same period of the previous fiscal year), and operating loss was ¥1,230,138 thousand (operating loss of ¥1,311,038 thousand in the same period of the previous fiscal year). In addition, the Company recorded interest income of ¥1,623 thousand and foreign exchange gains of ¥4,293 thousand as non-operating income, and interest expenses of ¥3,454 thousand, amortization of restricted stock remuneration of ¥3,274 thousand, share acquisition rights issuance costs of ¥7,412 thousand, and share issuance costs of ¥5,457 thousand as non-operating expenses, resulting in ordinary loss of ¥1,243,866 thousand (ordinary loss of ¥1,270,785 thousand in the same period of the previous fiscal year). As a result, loss was ¥1,246,692 thousand (net loss of ¥1,272,843 thousand in the same period of the previous fiscal year).

(2) Explanation of Financial Position

Assets at the end of the third quarter of the fiscal year under review were ¥2,397,188 thousand (17.5% increase compared with the end of the previous fiscal year), owing partly to an increase in advance payments – other. Liabilities were ¥434,555 thousand (23.3% decrease compared with the end of the previous fiscal year), owing partly to a decrease in accounts payable – other. Net assets were ¥1,962,632 thousand (33.1% increase compared with the end of the previous fiscal year), owing to increases in capital stock and legal capital surplus.

(3) Explanation of Financial Results Forecast and Other Forward-looking Information

The Company still has a small stable revenue base, and our financial results fluctuate greatly depending on the presence or absence of milestone revenue payments generated from our domestic distribution partnership agreement for OBP-301, achieving the development event of LINE-1 inhibitor OBP-601 by Transposon, and that company's IPO, M&A and other corporate action that generates milestone revenue payments.

For these reasons, we believe that it is difficult to calculate an appropriate and reasonable figure for the earnings forecast at this time due to the many undetermined factors that will affect our business performance, and therefore, we refrain from disclosing the forecast.

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly Balance Sheets

(Thousand yen)

	As of December 31, 2023	As of September 30, 2024
Assets		
Current assets		
Cash and deposits	1,532,844	1,643,155
Supplies	5,342	4,232
Advance payments – other	282,602	481,342
Prepaid expenses	33,338	62,856
Accounts receivable – other	51,781	66,946
Consumption taxes receivable	49,964	32,487
Other	9	50
Total current assets	1,955,883	2,291,071
Non-current assets		
Property, plant and equipment		
Buildings	3,128	3,128
Accumulated depreciation	(3,128)	(3,128)
Buildings, net	–	–
Machinery and equipment	924	924
Accumulated depreciation	(924)	(924)
Machinery and equipment, net	–	–
Tools, furniture and fixtures	66,967	70,241
Accumulated depreciation	(66,967)	(67,347)
Tools, furniture and fixtures, net	–	2,894
Total property, plant and equipment	–	2,894
Investments and other assets		
Shares of subsidiaries and associates	20,936	20,936
Investments in capital	100	100
Long-term loans receivable from subsidiaries and associates	42,549	42,846
Lease and guarantee deposits	20,990	22,174
Long-term prepaid expenses	135	17,162
Other	4	4
Total investments and other assets	84,714	103,222
Total non-current assets	84,714	106,116
Total assets	2,040,598	2,397,188

(Thousand yen)

	As of December 31, 2023	As of September 30, 2024
Liabilities		
Current liabilities		
Short-term loans payable	127,776	133,332
Lease obligations	7,565	5,404
Accounts payable – other	193,354	54,336
Accrued expenses	19,119	16,188
Income taxes payable	18,844	15,947
Deposits received	11,870	10,150
Total current liabilities	378,531	235,359
Non-current liabilities		
Long-term loans payable	161,100	177,768
Lease obligations	18,729	14,228
Provision for retirement benefits	8,140	7,199
Total non-current liabilities	187,969	199,196
Total liabilities	566,500	434,555
Net assets		
Shareholders' equity		
Capital stock	3,623,165	4,493,740
Capital surplus		
Legal capital surplus	1,209,590	2,080,069
Total capital surpluses	1,209,590	2,080,069
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(3,373,199)	(4,619,891)
Total retained earnings	(3,373,199)	(4,619,891)
Treasury shares	(142)	(142)
Total shareholders' equity	1,459,413	1,953,775
Share acquisition rights	14,683	8,857
Total net assets	1,474,097	1,962,632
Total liabilities and net assets	2,040,598	2,397,188

(2) Quarterly Statements of Income

Nine Months Ended September 30

(Thousand yen)

	For the nine months ended September 30, 2023	For the nine months ended September 30, 2024
Net sales	63,038	31,384
Cost of sales	32,433	–
Gross profit	30,604	31,384
Selling, general and administrative expenses	1,341,643	1,261,522
Operating loss	(1,311,038)	(1,230,138)
Non-operating income		
Interest income	1,007	1,623
Dividend income	3	5
Subsidy income	2,953	–
Foreign exchange gains	47,674	4,293
Other	177	22
Total non-operating income	51,816	5,945
Non-operating expenses		
Interest expenses	2,779	3,454
Amortization of restricted stock remuneration	629	3,274
Share acquisition rights issuance costs	–	7,412
Share issuance costs	8,155	5,457
Other	–	73
Total non-operating expenses	11,563	19,673
Ordinary loss	(1,270,785)	(1,243,866)
Extraordinary income		
Gain on sale of non-current assets	136	–
Total extraordinary income	136	–
Loss before income taxes	(1,270,649)	(1,243,866)
Income taxes - current	2,193	2,825
Total income taxes	2,193	2,825
Loss	(1,272,843)	(1,246,692)

(3) Notes to Quarterly Financial Statements

(Notes on going concern assumption)

There is no relevant information.

(Notes to statements of cash flows)

Quarterly statements of cash flows for the nine months ended September 30, 2024 are not prepared. Depreciation for the nine months ended September 30 is as follows:

(Thousand yen)

	For the nine months ended September 30, 2023	For the nine months ended September 30, 2024
Depreciation	680	380

(Notes in the case of significant changes in shareholders' equity)

The Company received payments for the exercise of the 19th series share acquisition rights during the nine months ended September 30, 2024. As a result, capital stock and legal capital surplus each increased by ¥322,649 thousand.

In addition, the Company issued new shares as restricted stock remuneration on April 2, 2024, based on the resolution by the Board of Directors at its meeting held on March 15, 2024. As a result, capital stock increased by ¥29,787 thousand and legal capital surplus increased by ¥29,691 thousand.

Furthermore, the 20th series share acquisition rights were issued as of July 1, 2024, and the Company received payments for the exercise of the rights. As a result, capital stock and legal capital surplus each increased by ¥518,138 thousand.

As a result of the above, capital stock increased by ¥870,575 thousand and legal capital surplus increased by ¥870,478 thousand during the nine months ended September 30, 2024. At the end of the period, capital stock was ¥4,493,740 thousand and legal capital surplus was ¥2,080,069 thousand.

(Segment information, etc.)

[Segment information]

I. For the nine months ended September 30, 2023

The information is omitted, as the Company consists of a single segment of the drug discovery business.

II. For the nine months ended September 30, 2024

The information is omitted, as the Company consists of a single segment of the drug discovery business.

(Revenue recognition)

Disaggregation of revenue from contracts with customers

(Thousand yen)

	For the nine months ended September 30, 2023	For the nine months ended September 30, 2024
Goods / Services transferred at a point in time	63,038	31,384
Goods / Services transferred over time	–	–
Revenue from contracts with customers	63,038	31,384
Revenue from other sources	–	–
Net sales to outside customers	63,038	31,384

(Per share information)

Loss per share and the basis for its calculation are as follows.

Item	For the nine months ended September 30, 2023	For the nine months ended September 30, 2024
Loss per share	¥(73.15)	¥(59.56)
(Basis for the calculation)		
Loss (Thousand yen)	(1,272,843)	(1,246,692)
Amount not attributable to common shareholders (Thousand yen)		–
Loss relating to common shares (Thousand yen)	(1,272,843)	(1,246,692)
Average number of shares during the period (shares)	17,399,785	20,932,636
Outline of the residual shares with significant changes from the end of the previous fiscal year among the residual shares that were not included in the calculation of diluted earnings per share because they have no dilutive effects	–	–

(Notes) Diluted earnings per share are not presented because of the posting of loss per share, although there are residual shares.

(Significant subsequent events)

Capital increase through exercise of share acquisition rights

During the period starting on October 1, 2024 and ending on October 31, 2024, a portion of the 20th series share acquisition rights was exercised as follows:

(1) Class and number of shares issued	shares of common stock
(2) Number of units of share acquisition rights exercised	units
(3) Total amount exercised	thousand yen
(4) Amount of increase in capital stock	thousand yen
(5) Amount of increase in legal capital surplus	thousand yen

(Notes) 1. (4) Amount of increase in capital stock and (5) Amount of increase in legal capital surplus include transfer of share acquisition rights of thousand yen each.

2. As a result of the above issuance of new shares upon exercise of stock acquisition rights, the total number of shares issued and outstanding as of October 31, 2024 was shares, capital stock was thousand yen, and legal capital surplus was thousand yen.

3. Supplemental Information

(1) Research and development activities

Research and development expenses of the Company in the nine months ended September 30, 2024 totaled ¥790,770 thousand for the drug discovery business. The status of research and development activities during the nine months ended September 30, 2024 is as follows.

(1) Research and development structure

As of September 30, 2024, 18 persons belonged to the research and development department, accounting for 47.4% of the total number of employees.

(2) Research and development and business activities

The Company promoted research and development, and business activities centered on the following projects.

1) Activities related to oncolytic virus OBP-301

The Company completed a "Phase II clinical trial (OBP101JP trial) in combination with radiation therapy for esophageal cancer" for OBP-301, for which the Ministry of Health, Labour and Welfare has granted "SAKIGAKE designation" for regenerative medicine products in Japan, and is in consultations with the Pharmaceuticals and Medical Devices Agency (hereinafter "PMDA") for submitting a new drug application in Japan. In February 2024, we signed an agreement with FUJIFILM Toyama Chemical Co., Ltd. (hereinafter "FUJIFILM Toyama Chemical") to collaborate with OBP-301 sales and established a supply chain for OBP-301 from Henogen SA (in the Thermo Fisher Group, Belgium), the manufacturer, to medical institutions providing treatments, as well as are promoting various consultations regarding a sales system after products are launched in the market. Furthermore, preparations are also underway to obtain approval for manufacture and sale of regenerative medical products.

Meanwhile, in the U.S., in December 2023, the Company signed an agreement with Cornell University, which in turn signed an agreement with Merch Sharp & Dohme LLC. (hereinafter "MSD"), to establish a joint development system for OBP-301 and the pembrolizumab. Based on this system, the Company and MSD equally share research and development expenses for a Phase II investigator-initiated clinical trial for the treatment of gastric cancer.

Currently, OBP-301 has undergone the following three clinical trials in Japan and overseas, including the clinical trial for which submitting an application for approval has been in preparation or enrollment has been completed:

i) Phase II clinical trial in combination with radiation therapy for esophageal cancer (OBP101JP trial);
ii) Phase II investigator-initiated clinical trial of second-line treatment in combination with immune checkpoint inhibitors for gastric cancer/gastroesophageal junction cancer; and
iii) Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer

i) **Phase II clinical trial in combination with radiation therapy for esophageal cancer (OBP101JP trial)**

This clinical trial was conducted based on the "SAKIGAKE designation" of April 2019 at 17 clinical trial sites around Japan and a notification of completion of clinical trial was submitted to PMDA in September 2024. The results of the clinical trial were deemed as detailed below, in consultations with medical experts and biological statisticians. Based on these results, the Company is currently in consultations with PMDA regarding non-clinical trials, clinical trials, manufacturing, etc. to submit a new drug application of OBP-301 in Japan.

Furthermore, the results of OBP101JP trial of OBP-301were presented by Dr. Akinori Watanabe, Department of Gastroenterology, Kitasato University School of Medicine at the 62nd Annual Meeting of Japan Society of Clinical Oncology held in Fukuoka in October 2024.

i-a) **Research and development activities**

Efficacy

The primary endpoint of "local complete response rate" (L-CR rate) was 41.7% (round off to the first decimal place; the same shall apply hereinafter), as evaluated by the Endoscope Central Judgment Committee. It was confirmed that the result was higher than the efficacy threshold of 30.2%, which was indicated in the protocol beforehand. In addition, the secondary endpoint of "local remarkable response rate" (L-RR rate; the cases in which the primary lesion did not completely disappear but shrink remarkably) was 16.7% and "local response rate" including L-RR ([L-CR + L-RR] rate) was 58.3%.

Furthermore, the one-year survival rate at the time of data cut-off in this study was 71.4%, which exceeded the one-year survival rate in the radiotherapy alone of 57.4% in "The Japan Esophageal Society national registered data."

At the time of 18 months, which is the longest follow-up period of this study, the local response rate was 63.9% and the local complete response rate was 50.0%. In addition, although the total survival rate at the time of 18 months was 53%, the cancer survival rate was 70% and the cancer survival rate of patients with local response was 90%.

Moreover, improvement was recognized in 71% of patients with symptoms of dysphagia, which is included in the assessment indicators of QoL (Quality of Life) for esophageal cancer patients. These results suggested a possible increase in patient survival rates from the effect of OBP-301 on esophageal cancer locations.

Safety

The main side-effects related to OBP-301 included fever of 51.4% and the reduction of lymphocyte count or lymphopenia of 48.6%, both of which were mild to moderate or temporary change.

i-b) **Business activities**

The significant supply chain for stable supply of OBP-301 is divided into the preceding process of "through manufacturer, import, and shipment" and the post-process of "from FUJIFILM Toyama Chemical to medical institutions." For OBP-301 sales, the Company needs to obtain approval for manufacture and sale of regenerative medical products, in addition to approval for a new drug.

Supply chain through manufacturer, import, and shipment

The Company is conducting commercial production and validation quality tests at Henogen SA, with a view to submitting a new drug application for OBP-301. Regarding virus-derived aggregates observed in the final drug formulation of OBP-301, their analysis and verification of the cause have been made, and a drug formulation with a new prescription that does not generate aggregates has also been developed. Furthermore, Eurofins Analytical Science Laboratories (Kyoto City), a party entrusted with the quality tests for OBP-301 after import, is preparing for establishment of a determination system for shipment of OBP-301. OBP-301, which will have been determined to be ready for shipment, will be shipped to FUJIFILM Toyama Chemical, our distribution partner.

Supply chain from FUJIFILM Toyama Chemical to medical institutions

The Company concluded a sales collaboration agreement with FUJIFILM Toyama Chemical in February 2024 to efficiently deliver OBP-301, which will have been determined to be ready for final shipment, to medical facilities in Japan. After a determination for shipment, OBP-301 will be shipped from the Company to FUJIFILM Toyama Chemical and provided to medical facilities through medical products companies designated by FUJIFILM Toyama Chemical. The Company concluded an agreement concerning safety information with FUJIFILM Toyama Chemical in September 2024. The Company will continue to conduct various consultations such as establishing a supply chain for smooth supply of OBP-301 after products are launched in the market.

Manufacture and sale of regenerative medical products

The Company will be positioned as a manufacturer and distributor shipping OBP-301 to Japan. Accordingly, before applying for approval of OBP-301, its manufacturing and marketing are subject to review by the Tokyo Metropolitan Government for conformity to "GQP (Good Quality Practice)," and "GVP (Good Vigilance Practice)" and other requirements, and the Company needs to obtain approval for manufacture and sale of regenerative medical products.

In January 2024, the Company completed the designation for the three roles of marketing director, quality assurance manager, and safety management manager for manufacturing and marketing, and also established the Reliability Assurance Division. Looking forward, we will further strengthen a system that conforms with GQP and GVP. Currently, the Company is preparing for an application to obtain approval for manufacture and sale of regenerative medical products.

ii) **Phase II investigator-initiated clinical trial of second-line treatment in combination with immune checkpoint inhibitors for gastric cancer/gastroesophageal junction cancer**

Regarding the above ii) "Phase II investigator-initiated clinical trial of second-line treatment in combination with immune checkpoint inhibitors for gastric cancer/gastroesophageal junction cancer," Cornell University in the U.S. proposed the implementation of a new clinical trial and the payment of clinical trial expenses to MSD, after obtaining the prior agreement of the Company. In December 2023, agreements were concluded between the Company and Cornell University and between Cornell University and MSD, which established a joint development system.

This clinical trial combines the use of OBP-301 and pembrolizumab as second-line treatment for patients with gastric/gastroesophageal junction cancer that is resilient to first-line treatment including anti- PD-1/PD-Li antibodies. Currently, the expenses for the clinical trial are shared equally between the Company and MSD, and administration is underway.

If this second-line treatment for gastric cancer combining OBP-301 becomes established, it may provide a greater opportunity for major pharmaceutical companies that sell anti- PD-1/PD-Li antibodies to prescribe immune checkpoint inhibitors. The Company expects that the results of this clinical trial will contribute to licensing activities for OBP-301 overseas.

iii) **Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer**

Regarding the above iii) "Phase I investigator-initiated clinical trial in combination with chemoradiotherapy for esophageal cancer," NRG Oncology, an authoritative cancer research organization in the U.S., has been leading the trial, and administration began in December 2021 with the purpose of investigating the safety and efficacy of using OBP-301 in combination with chemoradiotherapy. This clinical trial is being conducted in six facilities within the U.S., and the enrollment of the second stage is completed. Thus far, there have been no reports of problematic side- effects. OBP-301 has been designated as an orphan drug for esophageal cancer in the U.S., and this clinical trial is being conducted on that basis. Therefore, the Company will be able to receive preferential treatment in the form of grants and tax credits for clinical research expenses. Furthermore, first-mover rights protection will be granted after the approval of OBP-301 in the U.S., during which market exclusivity is to be granted.

2) Activities related to OBP-601 (censavudine), a LINE-1 inhibitor

The Company licensed in OBP-601 from Yale University in 2006. From 2010 to 2014, it was licensed to Bristol-Myers Squibb Co. (hereinafter "BMS"), which conducted Phase IIb clinical trials as a treatment drug for HIV infection. The results demonstrated the non-inferiority of OBP-601 to existing drugs. BMS also obtained numerous clinical safety data for long-term OBP-601 toxicity studies and oncogenicity studies, but due to BMS's change of strategy, resulting in withdrawal from the HIV field, the license agreement was terminated. Results of a study by Brown University of the U.S. then suggested that nucleic acid-based reverse transcriptase inhibitors (NRTIs) of HIV suppress the aberrant expression of a retrotransposons. Subsequent research confirmed that OBP-601, which has the same effect, has high brain translocability compared to other NRTIs and strongly suppresses the production of a retrotransposon by greatly inhibiting a reverse transcriptase called LINE-1.

In June 2020, we concluded a licensing agreement worth more than $300 million worldwide with Transposon which had been planning to apply OBP-601 to the treatment of intractable neurological diseases focusing on this mechanism. In November of the same year, Transposon achieved its first milestone.

Transposon completed two double-blind Phase IIa clinical trials that make use of placebos. One covers progressive supranuclear palsy (PSP), while the other is on amyotrophic lateral sclerosis (ALS), with the abnormal expression of the enzyme C9 ORF, and frontotemporal degeneration (FTD). In addition, enrollment is proceeding under a single-arm Phase IIa clinical trial in Europe for the treatment of Aicardi-Goutières Syndrome (AGS).

These clinical trials on OBP-601 are proceeding entirely at Transposon's expense based on the license agreement. In addition, Transposon is carrying out business activities based on the license agreement and may grant sublicenses for OBP-601 to pharmaceutical companies and other third parties. If Transposon achieves business results, including sublicense agreements for OBP-601 with third parties, it will pass on a certain percentage of revenue it obtains from the sublicensees to the Company.

Transposon is a company that was established with the purpose of developing OBP-601. The Company therefore believes that the risk of Transposon suspending the development of OBP-601 due to a change in strategy is low and expects Transposon to achieve business results.

i) **Phase IIa clinical trial for PSP**

Administration to the first patient under the Phase IIa clinical trial for PSP began in November 2021, and enrollment of the target number of patients was concluded in August 2022. Transposon disclosed the main details of the trial as follows at the 18th Alzheimer's and Parkinson's Diseases Conference (AD/PD2024) in March 2024.

1) The clinical trials incorporated 42 PSP patients with an average age of 69 years and an average illness duration of 3.8 years.
2) In these double-blind trials, administration was conducted for 6 months, then administration was switched to 400 mg of OBP-601 for all patients and follow-up was provided for 6 months.
3) OBP-601 indicated tolerability for PSP patients, and loss of consciousness (1 patient in the 100 mg group) was reported as a serious side effect.
4) Regarding the reduction of neurofilament light chains (hereinafter "NfL") in cerebrospinal fluid, continued reduction in the 400 mg administration group was indicated, but in the placebo group an increase over 24 weeks and then a reduction after switching to 400 mg administration at the start of the follow-up period were indicated.
5) IL-6 indicated a similar change in cerebrospinal fluid.
6) OBP-601 slowed the worsening of symptoms measured on the Progressive Supranuclear Palsy Rating Scale (PSPRS).
7) With these above results, the clinical trials suggested that OBP-601 suppresses neurological damage from inflammation and the progression of illness by suppressing Line-1 in the brain.

Transposon is currently moving forward on specific preparations for Phase III clinical trials for PSP with the U.S. Food & Drug Administration (FDA), such as holding the End of Phase II meeting to aim for starting Phase III clinical trials for PSP in parallel with business activities. OBP-601 received *Fast Track* designation from FDA in May 2024.

ii) **Phase IIa clinical trial for C9-ALS/FTD**

Administration under the clinical trial for C9-ALS/FTD began in January 2022, and target enrollment was concluded in March 2023. We have also completed a long-term follow-up study on the enrolled patients. To date, there have been no reports of safety problems that necessitate the termination of the trials. Transposon presented the development status for ALS at the 2024 Annual Northeast Amyotrophic Lateral Sclerosis Consortium (NEALS) Meeting in October 2024. The main final analysis results of the trial related to ALS after 48 weeks are as follows:

1) The OBP-601 administration group reduced primary biomarkers of neurodegeneration and neuroinflammation including NfL, neurofilament heavy chains (hereinafter "NfH"), and IL-6.
2) The assessment using a scale for assessment of ALS function (ALSFRS-R) indicated effects of suppressing the progression of illness.
3) The OBP-601 administration group decreased the deterioration rate of Vital Capacity, which is an objective indicator of respiratory function that correlates with C9-ALS patient mortality, by approximately 50% compared with the placebo administration group in the 24 weeks from the start of administration.
4) The OBP-601 administration group indicated a decrease in significant values of NfL in a meta-analysis that comprehensively analyzed Phase II clinical trials for C9-ALS/FTD and PSP.
5) Transposon plans to move forward with Phase III clinical trials on OBP-601 for C9-ALS.

iii) **Phase IIa clinical trial for AGS**

In July 2023, Transposon started administration under a new Phase IIa clinical trial for AGS, a genetic disorder that causes microcephaly and severe mental retardation, in Europe. To date, there have been no reports of safety problems that necessitate the termination of the trials.

3) Activities related to next generation oncolytic virus OBP-702

OBP-702 is a second-generation virotherapeutic drug with two anti-tumor effects, combining the "oncogene therapy" that uses a novel oncolytic virus that carries the powerful in vivo cancer suppressor gene p53 in the vector with the "oncolytic functions" of OBP-301. A research group led by Professor Toshiyoshi Fujiwara of the Department of Gastroenterological Surgery, Transplant, and Surgical Oncology of Okayama University is conducting non-clinical trials on OBP-702, which was adopted as a grant program by the Japan Agency for Medical Research and Development (AMED). In particular, an experiment on gemcitabine-resistant pancreatic cancer cell lines using mouse models, OBP-702, used in combination with PD-L1 antibodies, exhibited stronger anti-tumor effects alone. It has also been shown to have a lethal effect on cancer associated fibroblasts (CAF), which are problematic in cancer therapy. It is expected that OBP-702 will be developed as a new treatment method for pancreatic cancer and other refractory cancers that are considered to be difficult to treat due to CAF. Development of OBP-702 will continue within the scope of the grant in order to concentrate management resources on OBP-301 to submit for approval.

4) Activities related to OBP-2011 for the treatment of viral infectious diseases

Based on experimental outcomes, the Company assumes that OBP-2011 inhibits nucleocapsids, although the specific mechanism has not been clarified yet at this stage. It is speculated that OBP-2011 has a new mechanism that differs from the main mechanisms of polymerase and protease inhibition already approved for the treatment of coronaviruses, and data indicated that its effectiveness is not influenced by such factors as virus mutation. However, it has become necessary to revise the development policy as the hurdle has been raised for obtaining approval for our proposed COVID-19 treatment, at the same time as changes have emerged in the external environment, such as the reduced urgency due to the launch of multiple therapeutic drugs for COVID-19 to the market, and the concentration of management resources on OBP-301 to apply for approval. Going forward, the Company will proceed with clarifying the detailed mechanism of action for OBP-2011 by conducting collaborative research with Kagoshima University and will consider new indications for RNA viruses other than coronaviruses, maintaining a framework that can respond to new pandemics.

5) Activities related to TelomeScan (OBP-401), a cancer detection drug

The Company is conducting image learning of live cancer cells within the blood that TelomeScan fluoresced for automatic judgment by AI, aimed at establishing a platform for automated detection. However, the development has been delayed due to more time required to acquire the large number of images for image learning than initially planned. We have lowered the priority of these activities in order to concentrate management resources on OBP-301 to submit for approval.

6) Activities related to OBP-801, HDAC inhibitor

Regarding OBP-801, a histone deacetylase (HDAC) inhibitor licensed from Astellas Pharma Inc. in 2009, dose limiting toxicity (DLT) was observed in Phase I clinical trials targeting solid body cancers in the U.S., making it impossible to escalate the dosage to the presumed effective dose. Therefore, development in the field of cancer has been suspended.

On the other hand, research for application to glaucoma surgery has been carried out at the Department of Ophthalmology of Kyoto Prefectural University of Medicine in the ophthalmic field, which is a new area of indication for OBP-801, revealing that the drug suppresses fibrosis after filtering bleb formation from glaucoma surgery. The research results were presented at a meeting of the Japanese Ophthalmological Society in April 2023 and at an annual meeting of the Association for Research in Vision and Ophthalmology (ARVO). Furthermore, use invention of OBP-801 related to “suppression of filtering bleb fibrosis after glaucoma surgery” and “age-related macular degeneration” received patents in Japan in July 2024. We have lowered the priority of these activities in order to concentrate management resources on OBP-301 to submit for approval.

The development status of pipeline products is as follows.

Product	Indication	Combination therapy	Development region	Development stage
OBP-301 (suratadenoturev)	Esophageal cancer	Radiation therapy	Japan	Phase II complete (NDA preparation)
		Chemoradiotherapy	U.S.	Phase I
		Anti-PD-1 antibody pembrolizumab	Japan	Phase I (complete)
	Gastric/ gastroesophageal junction cancer	Anti-PD-1 antibody pembrolizumab	U.S.	Phase II (complete)
		Immune checkpoint inhibitor pembrolizumab	U.S.	Phase II
	Hepatocellular cancer (HCC)	Monotherapy	South Korea and Taiwan	Phase I (complete)
OBP-601 (censavudine)	Progressive supranuclear palsy (PSP)	Monotherapy	U.S.	Phase IIa (Phase III preparation)
	Amyotrophic lateral sclerosis (C9-ALS) / frontotemporal degeneration (FTD)	Monotherapy	U.S. and Europe	Phase IIa (Phase III preparation)
	Aicardi-Goutières Syndrome (AGS)	Monotherapy	Europe	Phase IIa
OBP-702	Solid tumor	Anti-PD-(L)1 antibody (expected)	Japan	Pre-clinical
OBP-2011	Viral infectious diseases	TBD	Japan	Pre-clinical
TelomeScan (OBP-401)	Solid tumor	—	Japan	Clinical research
OBP-801	Suppression of filtering bleb fibrosis after glaucoma surgery	—	Japan	Pre-clinical